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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,162	09/18/2003	Jinhu Xiong	ACC.0002US	7082

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EXAMINER

LAMPRECHT, JOEL

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/666,162	Applicant(s) XIONG ET AL.	
	Examiner Joel M. Lamprecht	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-21,23,25-32 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-21,23,25-32 and 34-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-5, 12-17, 21-25 and 34-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Jenkins et al. (U.S. Patent No. 6,321,105).

3. Regarding Claims 1-5, 14-17, 23-25 and 34-36, Jenkins et al. teaches a method of magnetic resonance imaging including detecting regional neural activity in a subject based on transient magnetic fields induced by the activity, spatially and temporally localizing the regional neural activity using at least a portion of the detected transient magnetic fields, directly mapping electromagnetic activity of the subject and producing an image of the region, where the magnetic resonance imaging comprises applying an asymmetric pulse sequence to the subject, where the asymmetric pulse sequence is a gradient-echo echo-planar image pulse sequence that has a repetition time of between approximately 40 and 10,000 milliseconds, an echo time of between approximately 10 and 200 milliseconds and a flip angle of between approximately 10 and 180 degrees and where detecting the magnetic resonance imaging signal includes measuring magnitude changes (col. 1, lines 48-65, col. 2, lines 60-67, col. 3, lines 1-12 and col. 7, lines 1-20).

4. Specifically regarding Claims 23-25 and 34-36, it is inherent within the use of an MRI apparatus that the instructions for performing a scanning procedure of any kind would necessarily be stored on a computer readable medium because the magnitude and complexity of such instructions require that the procedure be run by computer.

Regarding Claims 12, 13, 21 and 22, Jenkins et al. teaches diagnosing a disorder of a nervous system of the subject using the regional neural activity, analyzing a drug effect on a nervous system of the subject using the regional neural activity and measuring latency of the electromagnetic activity (col. 2, lines 50-59 and col. 7, lines 21-37).

5. Claims 37, 38, are rejected under 35 U.S.C. 102(e) as being anticipated by Jenkins. Jenkins discloses all listed above previously, and also discloses detection regional neural activity prior to or after hemodynamic activity in the subject as a result of regional neuronal activity. Jenkins also discloses direct mapping of EM activity based on MRI data obtained in a window of time prior or after hemodynamic activity in the subject as a result of regional neuronal activity.

6. Claims 26-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Biswal et al. (U.S. Patent No. 6,477,39).

7. Biswal et al. teaches a system including a magnetic resonance imaging scanner having a plurality of magnets to generate a magnetic field around a subject, a controller coupled to the scanner to detect a magnitude of magnetic resonance signals representing a neuronal magnetic field, a second controller coupled to the magnetic resonance imaging scanner to provide an asymmetric pulse sequence to the scanner, a stimulus generator to provide a stimulus to the subject and a measurement device to

measure the subject's response to the stimulus, where the plurality of magnets includes a main magnet and a gradient magnet, where the controller is further adapted to directly map electromagnetic activity of the subject via the magnitude of the magnetic resonance signals, where the map is a spatial and temporal localization of neuronal activity of the subject and where the controller is adapted to measure latency of the electromagnetic activity (col. 5, lines 14-27 and 52-60, col. 6, lines 41-56 and 63-67 and col. 7, lines 1-43).

8. Claims 39, and 40 are rejected under 35 U.S.C 102(b) as being anticipated by Kamei et al. Kamei et al. disclose instructions and a controller (4109-4110) to detect regional neural activity in a predetermined window prior to hemodynamic activity in the subject as a result of regional neural activity.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 6, 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al. in view of Frederick et al. (U.S. Patent No. 6,104,943). Jenkins et al. teaches all of the features of the present invention except for expressly disclosing stimulating the subject with a hemodynamically neutral stimulation where the stimulation includes providing rapid stimuli to the subject. In the same field of endeavor, Frederick et al. teaches stimulating the subject with bilateral visual stimulation at a rate of 8 Hz

(col. 6, lines 8-22). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a stimulus as in Frederick et al. with the system of Jenkins et al. in order to provide additional variance in the neuronal response without administering additional drugs to the patient.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al. in view of Frederick et al. as applied to Claim 7 above, and further in view of Rosenfeld et al. (U.S. Patent No. 6,370,416).

12. Jenkins et al. in view of Frederick et al. teaches all of the features of the present invention except for expressly disclosing causing the subject to perform a motor activity in response to the rapid stimuli. In the same field of endeavor, Rosenfeld et al. teaches providing a subject with a pulsed stimulation simultaneous to requiring performance of an activation task such as touching a finger to a thumb (col. 6, lines 38-63). It would have been obvious to one of ordinary skill in the art at the time of the invention in order to analyze neural activity associated with motor activity in addition to that associated with visual or auditory stimuli.

13. Claims 9-11, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al. in view of Mueller (U.S. Patent No. 6,289,234). Jenkins et al. teaches all of the features of the present invention except for expressly disclosing performing a second nervous system measurement technique to conjoin with the magnetic resonance imaging and detecting intrinsic rhythms of a nervous system of the subject using the regional neural activity, where the second nervous system measurement technique measures at least one of cerebral hemodynamic, metabolic,

and neural activity. In the same field of endeavor, Mueller teaches monitoring a subject's neural activity via EEG during a magnetic resonance scan and detecting intrinsic rhythms of the subject's activity (col. 3, lines 3-25). It would have been obvious to one of ordinary skill in the art at the time of the invention to monitor a subject with a second modality in order to provide additional information about the condition and activity of the subject.

Response to Remarks/Arguments

14. In regard to the remarks filed on 12/27/2005, Applicants have canceled claims 8, 22, 24, and 33, Applicants have amended none of the claims, and Applicants have added claims 37, 38, 39, and 40; the Examiner has fully considered the remarks.

15. In regard to Applicants' remarks that the reference nowhere teaches detecting regional neural activity based on transient magnetic fields induced by regional neural activity – the Examiner respectfully disagrees. Jenkins clearly teaches detecting regional neural activity based on transient magnetic fields induced by regional neural activity (col. 2, line 60-66), and it is of no consequence that the hemodynamic response could influence or modify the regional neural activity as per Applicants' claim limitations.

16. In regard to Applicants' remarks that the reference does not teach directly mapping EM activity of a subject via MRI – the Examiner respectfully disagrees. Jenkins teaches detecting a method for performing MRI and directly mapping EM activity of the subject via the MR imaging. The method taught by Jenkins directly maps the EM activity, even if BOLD method MRI captures are a hemodynamically dependent measure of neuronal activity.

17. In regard to Applicants' remarks that the reference does not teach a controller that detects a magnitude of magnetic resonance signals that represent a neuronal magnetic field – the Examiner respectfully disagrees. Biswal teaches a controller that detects magnitude signals representing a neuronal magnetic field, and Applicants' cited (col. 2 lines 15-25) passage is simply reasons for variability amongst readings of NMR signals (the hemodynamic effects). The measurements taught by Biswal are still based on magnitude signals representing a neuronal magnetic field.

18. In regard to Applicants' remarks about claims 6, 7, 9-11 and 18-20, the rejection of the aforementioned claims is upheld for the reasons listed above.

19. Applicants' arguments have been fully considered but have been found unpersuasive.

Conclusion

20. The Examiner would like to take note to the Applicants that if a continued examination is requested in the future, further distinction and evidence is respectfully requested to sustain a basis of patentability for the claimed invention. Specifically, if the Applicants wish to take credit for detection of all modalities of regional neuronal activity, based on any sort of stimuli, as a next-to-immediate, nonhemodynamic, direct mapping of solely neuronal currents in humans, some sort of additional disclosure on the effectiveness of the visual-based stimuli is required. Also requested is a measure of how this technique defines the totality of neuronal cortical surfaces. As it appears, and as shown in the reference used in the rejection of Claims 39 and 40, phantom simulation is used to approximate a dipole, lacking the nebulousness attributed by most

to surface field distributions. Therefore, this method of "msMRI" would only pertain to situations where it can be approximated, or presumed that neuronal bundles comprise a net field distribution devoid of inhomogenities.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JML
8/21/06

Guy Vidulich
SPE
TC 3700